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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,896	12/21/2001	Viktor Roschke	PA004P1	5432
22195	7590	10/03/2003	EXAMINER	
HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE, MD 20850			KENEDY, ANDREW A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/023,896	ROSCHKE, VIKTOR	
	<b>Examiner</b>	<b>Art Unit</b>	
	Andrew A. Kenedy	1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 14-15, and 22 drawn to an isolated nucleic acid molecule comprising a polynucleotide and the making of an isolated polypeptide from a recombinant cell, classified in at least class 536, subclass 23.1.
  - II. Claims 11-12 and 16 drawn to an isolated polypeptide comprising an amino acid sequence, classified in at least class 530, subclass 300.
  - III. Claim 13, drawn to an isolated antibody that binds specifically to the isolated polypeptide, classified in at least class 530, subclass 387.1.
  - IV. Claim 17, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering...the polypeptide, classified in at least class 514, subclass 2.
  - V. Claim 18, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering...the polynucleotide, classified in at least class 514, subclass 44.
  - VI. Claim 19, drawn to a method of diagnosing a pathological condition in a subject comprising determining the presence or absence of a mutation in the polynucleotide, classified in at least class 435, subclass 6 and class 436, subclass 63.
  - VII. Claim 20, drawn to a method of diagnosing a pathological condition in a subject comprising determining the presence or amount of expression of the polypeptide, classified in at least class 435, subclass 7.1 and class 436, subclass 63.
  - VIII. Claim 21, drawn to a method for identifying a binding partner to the polypeptide, classified in at least class 436, subclass 501.
  - IX. Claim 23, drawn to a method of identifying an activity in a biological assay...comprising detecting the activity and identifying the protein in the supernatant having the activity, classified in a least class 436, subclass 86.
  - X. Claim 24, drawn to a product produced by the method of claim 20. Since claim 20 is not a method that produces a product, it is assumed that this is a typographical error and should instead read to the product produced by the method of Claim 23. As such, this claim is classified in class 530, subclass 350.

2. Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to polypeptide sequences, the Applicant must elect only one (1) polypeptide sequence for examination. For an elected Group drawn to nucleotide sequences, the Applicant must elect only one (1) nucleotide sequence for examination (See M.P.E.P. § 803.04).

M.P.E.P. § 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that one (1) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of one (1) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Applicant is requested to specifically identify a single SEQ ID NO:X, SEQ ID NO:Y, and ATCC Deposit No:Z in the response.

Applicant is advised that examination will be restricted to only the elected SEQ ID Number, and this should not be construed as a species election.

3. The inventions are distinct, each from the other for the following reasons:

Each of the products of Groups I, II, III, and X are distinct, each from the other, because they are different chemical compounds. Each would require a non-coextensive literature search.

Each of the methods of Groups IV, V, VI, VII, VIII, and IX are distinct, each from the other, because they have different materials, method steps, and/or goals. Each method would require a non-coextensive literature search.

The products of Groups I, II, III, and X are independent inventions from the methods of Groups IV, V, VI, VII, VIII, and IX because the products can be used for additional methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or requirements for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew A. Kenedy whose telephone number is 703-305-4842. The examiner can normally be reached on Monday-Friday, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Andrew A. Kenedy  
Examiner  
Art Unit 1631

AAK  
September 29, 2003

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1800  
*Art 1631*